Attorney Docket No.: 100727-50/Heraeus 402-KGB
Confirmation No.: 6455

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS	:	Dr. Martin GRUNWALD, et al.
SERIAL NO.	:	10/600,773
FILED	:	June 20, 2003
FOR	:	PROCESS FOR THE STERILIZATION AND/OR GERM REDUCTION OF MOLD MATERIALS
ART UNIT	:	1797
EXAMINER	:	Eliazabeth L. MCKANE

MAIL STOP APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 5, 2009

APPELLANTS' BRIEF ON APPEAL PURSUANT TO 37 CFR § 41.37

MADAM:

This is an appeal from the final rejection of claims 1, 2, 6, 7, 9-12, 16, 17 and 19 of the present application from Art Group 1797.

(1) REAL PARTY IN INTEREST

The real party in interest for this appeal and the present application is HERAEUS KULZER GMBH (previously known as "HERAEUS KULZER GMBH & CO. KG") by virtue of an assignment recorded in the United States Patent and Trademark Office on December 15, 2003, at Reel 014195, Frame 0018.

(2) RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences or judicial proceedings, known to Appellants, Appellants' representative, or the Assignee, that may be related to, or that will directly affect or be directly affected by or have a bearing upon, the Board's decision in the pending appeal.

(3) STATUS OF CLAIMS

Claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are pending.

Claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are rejected.

Claims 3-5, 8, 13-15 and 18 are canceled.

Claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are on appeal.

(4) STATUS OF AMENDMENTS

In response to the Final Office Action dated June 24, 209, Appellants filed a Notice of Appeal. There are no outstanding amendments.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

The present application contains one independent claim, viz., claim 1. Claims 2, 6, 7, 9-12, 16, 17 and 19 depend either directly or indirectly from claim 1.

Independent claim 1 relates to a process for the sterilization and/or germ reduction of elastomeric two-component dental molding materials (see page 6, lines 2 and 3, page 8, lines 6-8, page 9, lines 12-15 and page 10, lines 11 and 12). The process comprises the steps of providing two components of the dental molding materials (see page 9, lines 12-15, page 10, lines 11 and 12 and Example 4), wherein at least one component of the two components comprises a polymer having one or more functional groups (see page 8, lines 15-18, page 10, lines 18-20, page 13, lines 5-8, page 16, lines 5-10, page 19, lines 9-11 and page 8, line 29 – page 9, line 2). The at least one component comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions (see page 8, lines 13-20, page 10, line 13-15, page 12, lines 3 and 4, page 13, line 8, page 16, lines 18-20, page 19, lines 7-11 and Examples 1, 2 and 5), ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction (see page 10, lines 13-15, page 12, lines 4 and 5, page 13, lines 5-8 and Examples 1, 2 and 5), iii) ring opening polyether impression materials via an aziridino group (see page 10, lines 13-15, page 12, lines 4 and 5, page 13, lines 5-8 and Examples 1, 2 and 5), or iv) polyether impression materials which are cross-linkable by condensation reaction (see page 10, lines 13-15, page 12, lines 4 and 5, page 13, lines 5-8 and Examples 1, 2 and 5). The process further comprises the step of subjecting the two components in an unmixed state in a primary packing

agent to radiation sterilization (see page 8, lines 13-20, page 9, line 24 – page 10, line 3, page 10, line 30, page 11, line 1, page 13, lines 3-8 and Examples 1, 2, 4 and 5).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

I. Whether claims 1, 2, 9-11 and 19 are unpatentable under 35 USC 103(a) over the combination of U.S. Patent No. 6,121,362 to Wanek et al. (hereinafter "Wanek") and U.S. Patent No. 6,547,467 to Quintero et al. (hereinafter "Quintero");

II. Whether claims 6, 7 and 16 are unpatentable under 35 USC 103(a) over the combination of Wanek and Quintero further in view of U.S. Patent No. 4,741,966 to Cavezzan; and

III. Whether claims 12 and 17 are unpatentable under 35 USC 103(a) over the combination of Wanek and Quintero further in view of U.S. Patent No. 5,540,876 to Larson et al. (hereinafter "Larson").

(7) ARGUMENT

As will be detailed below, (1) the combination of Wanek in view of Quintero does not teach or suggest all of the features recited in process claims 1, 2, 9-11 and 19, (2) the combination of Wanek and Quintero in view of Cavezzan does not teach or suggest all of the features recited in process claims 1, 6, 7 and 16 and (3) the combination of Wanek and Quintero in view of Larson does not teach or suggest all of the features recited in the process claims 1, 12 and 17.

A. Claims 1, 2, 9-11 and 19 Would Not Have Been Obvious over Wanek in view of Quintero

Claims 1, 2, 9-11 and 19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wanek in view of Quintero.

As set forth in pages 2 and 3 of the final Office Action, the Examiner alleges that:

(1) Wanek teaches each and every feature of independent claim 1 except radiation sterilization of the separate components within the double-chambered cartridge;

(2) Quintero remedies the deficiencies of Wanek by allegedly teaching that it was known in the art at the time of the invention to package two separate, unmixed components within a packaging device wherein the entire assembly is then sterilized with gamma radiation;

(3) Quintero (a) evidences packaging a polymerizable and/or crosslinkable monomer and polymerization initiator or accelerator within distinct and separate parts of a packaging syringe to prevent crosslinking or polymerizing prior to use, (b) teaches the syringe and its contents are then sterilized with gamma radiation, and (c) teaches a final polymeric composition used in medical application; and

(4) it would have been obvious to one of ordinary skill in the art to (a) sterilize the composition of Wanek since Quintero evidences that compositions intended for in vivo use must first be sterilized and (b) radiation sterilize the components of Wanek within the dual-chamber catridge of Wanek as Quintero discloses that it was known in the art to achieve a sterile and non-crosslinked/polymerized product using radiation sterilization.

Appellants respectfully disagree with the allegations made by the Examiner.

The Examiner erred by determining that Quintero remedies the acknowledged deficiencies of Wanek. Quintero is directed to the presentation of adhesives/sealants on biological substrates by means of a micro-applicator. However, Quintero fails to teach use of the adhesives/sealants in dentistry or as molding materials (hereinafter "MMs") as recited in claim 1.

In principle, MMs, such as Wanek's silicone-based impression material and the presently claimed impression materials, should reproduce the surface structure of the tooth and are not intended to remain on the structure of the tooth. This is a basic difference between Wanek's silicone-based impression material, the presently claimed impression materials and Quintero's adhesives/sealants. However, there is no teaching or suggestion in Wanek or in its combination with Quintero that would have suggested that sterilizing adhesives/sealants which remain on a tooth structure as described in Quintero would be useful to the silicone-based impression material which reproduces surface structure of a tooth and does not remain on a tooth structure as described in Wanek. Absent such teaching or suggestion in Wanek or in its combination with Quintero, persons ordinarily skilled in the art would not have had a

motivation to sterilize the silicone-based impression material according to Wanek with irradiation described in Quintero as alleged by the Patent Office.

Because Wanek's silicone-based impression material and Quintero's adhesives/sealants are so different, the skilled artisan would not have looked to use teachings related to adhesive/sealants in silicone-based impression material. Accordingly, a skilled artisan would not have been motivated to combine the teachings of Quintero with Wanek to achieve the presently claimed invention.

Another difference between Wanek's silicone-based impression material and Quintero's adhesives/sealants is that the presently claimed invention and Wanek's silicone-based impression material are pastes (see col. 4, lines 26-28 and 55, col. 7, lines 32-34, col. 8, lines 11-18, 46-51 and 62-67 and Tables 1 and 2 of Wanek), while Quintero's adhesives/sealants are monomeric liquid adhesive compositions (see col. 18, lines 46-48 of Quintero). However, there is no teaching or suggestion in Wanek or in its combination with Quintero that would have suggested that sterilizing monomeric liquid adhesive compositions as described in Quintero would be useful to the silicone-based impression material of Wanek. Absent such teaching or suggestion in Wanek or in its combination with Quintero, persons ordinarily skilled in the art would not have had a motivation to sterilize the silicone-based impression material according to Wanek with irradiation described in Quintero as alleged by the Patent Office.

Because Wanek's silicone-based impression material and Quintero's monomeric liquid adhesive composition are so different, the skilled artisan would not have looked to use teachings of monomeric liquid adhesive compositions in silicone-based impression material.

Accordingly, a skilled artisan would not have been motivated to combine the teachings of Quintero with Wanek to achieve the presently claimed invention.

Present claim 1 requires that at least one component of the two component comprises a polymer having one or more functional groups. The present two-component system which is suitable for dental moldings consists of polymers with at least one functional group (i.e., vinyl group and SiH groups or OH groups and Si-O alkyl groups in the case of silicone impression materials and aziridino groups in the case of polyether impression materials as recited in present claim 19). The presently claimed two-component system comprises polymers with functional groups because of the desire to be able to remove these polymers intact from the mouth after a short period and the desire that the polymers with functional groups naturally do not adhere to a tooth substance, unlike the adhesives/sealants according to Quintero.

In contrast, Quintero's adhesives/sealants naturally adhere to the tooth substance and most importantly only consist of monomers with optional auxiliary agents. Specifically, Quintero's adhesives are (cyano)acrylate-containing monomers with optional auxiliary agents. At best, Quintero teaches gamma radiation sterilization of two separate, unmixed components, namely polymerizable and/or crosslinkable (cyano)acrylate-containing monomers and a polymerization initiator or accelerator, as acknowledged by the Examiner in the paragraph bridging pages 2 and 3 of the June 24, 2009 Final Office Action. Thus, Appellants submit that Quintero fails to teach or suggest subjecting two components of the dental molding materials, which requires at least one component comprise a functional polymer, in an unmixed state to radiation sterilization as recited by claim 1.

Because Quintero is directed to radiation sterilization of polymerizable and/or crosslinkable monomers and a polymerization initiator or accelerator for adhesives/sealants on biological substrates, a skilled artisan would not have turned to Quintero's adhesives/sealants to modify Wanek's impression material. Moreover, even if the skilled artisan modified Wanek with Quintero, the resulting combination would fail to achieve the presently claimed invention because Wanek and Quintero both fail to teach or suggest radiation sterilization of at least one component of a two component system, in an unmixed state, comprising a polymer having one or more functional groups.

As discussed in the last paragraph on page 4 of the present application, it is desirable to eliminate danger of germ infestation associated with impression materials without changing the properties of the impression materials. However, prior art teaches that previous attempts to sterilize impression materials severely change elasticity of impression material such that the sterilized impression material is no longer usable as elastomeric impression material (see the third and fourth paragraphs on page 5 of the present application). Additionally, prior art teaches that sterilization by high radiation doses result in changes in properties (radiation cross-linking and degradation of polymer structures) such that lasting properties of impression materials were not to be expected (see the second paragraph on page 6 of the present application).

As set forth in the present application, the presently claimed process produces dental molding materials with surprising and unexpected characteristics in view of the prior art. The presently claimed process surprisingly and unexpectedly produces dental molding materials which, even after being subjected to radiation sterilization in comparatively high radiation

doses (i.e., 40 kGy), do not exhibit changes or only minor changes in application-technical properties or physical properties, such as appearance of pre-cross-linkings, occurrence of radiation cross-linking, partial chain-decomposition, viscosity reduction (see the fourth paragraph on page 8 to the first full paragraph on page 9 and Examples 1, 2, 4 and 6 of the present application).

Example 1 of the present application illustrates comparative data for the presently claimed two component systems irradiated in twin-chamber cartridges with gamma rays of 25 kGy compared to untreated samples. As discussed in the present application, it was expected that high-energy radiation sterilization would cause changes in the properties of the two component systems, such as radiation cross-linking and degradation of polymer structures (see the second full paragraph on page 6 of the present application). However, the results in Example 1 unexpectedly show good stability and acceptable ranges of change in kinetics and viscosity for the irradiated samples.

Present Example 2 illustrates comparative data for the presently claimed two component systems which were untreated and treated with gamma radiation of 20 kGy and/or 40 kGy. The presently claimed two component systems retain good application properties after radiation treatment such that they remain usable as impression material despite minor changes in properties (i.e., viscosity, elastic-viscous behavior and/or cross-linking kinetics) that occur from the radiation treatment.

Example 4 of the present application illustrates comparative data for the presently claimed two component systems which were untreated and treated with gamma radiation of 25

kGy. After gamma radiation treatment, the presently claimed two component systems exhibit a low or negligent increase in viscosity with a concurrent cross-linking kinetic acceleration.

Present Example 6 illustrates comparative data for the presently claimed two component systems in non-sterilized condition and after an electron ray sterilization with a dose of 25 kCy each. Example 6 shows, analogous to the results of gamma ray treatment (see Examples 1, 2 and 4 of the present application), the electron ray treated samples exhibit only minor influence on the physical properties (i.e., viscosity increase and kinetic acceleration) of the treated samples such that the treated samples remain useable after electron ray treatment.

Thus, the surprising and unexpected results illustrated in Examples 1, 2, 4 and 6 further support nonobviousness of the presently claimed process over the prior art and cited references.

Accordingly, neither Wanek nor Quintero, taken singly or in combination, teaches or suggests the step of subjecting the two components of dental molding materials in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups and further comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions, ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction, iii) ring opening polyether impression materials via an aziridino group or iv) polyether impression materials which are cross-linkable by condensation reaction as required by claim 1.

Because these features of independent claim 1 are not taught or suggested by Wanek and Quintero, taken singly or in combination, these references would not have rendered the features of claim 1 and its dependent claims obvious to one of ordinary skill in the art.

In view of the foregoing, the combination of Wanek and Quintero could not possibly lead to Applicants' invention, and the rejection of claims 1, 2, 9-11 and 19 under 35 U.S.C. 103(a) as unpatentable over Wanek and Quintero should now be reversed.

B. Claims 6, 7 and 16 Would Not Have Been Obvious over the Combination of Wanek and Quintero in view of Cavezzan

Claims 6, 7 and 16 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Wanek and Quintero in view of Cavezzan.

The Examiner alleges that modifying the combination of Wanek and Quintero with the teachings of Cavezzan achieves the features of claims 6, 7 and 16. Appellants respectfully disagree with the allegations by the Examiner.

Appellants' submit that Cavezzan does not remedy the deficiencies of the combination of Wanek and Quintero as set forth above with respect to claim 1, from which claims 6, 7 and 16 directly or indirectly depend, because Cavezzan also fails to teach or suggest a step of subjecting the two components of dental molding materials in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups.

Thus, Wanek, Quintero and Cavezzan, taken singly or in combination, fail to teach or suggest a step of subjecting two components of dental molding materials in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two

components comprises a polymer having one or more functional groups and further comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions, ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction, iii) ring opening polyether impression materials via an aziridino group or iv) polyether impression materials which are cross-linkable by condensation reaction as required by claim 1.

Accordingly, the combination of Wanek with Quintero and Cavezzan could not possibly lead to Appellants' invention, and the rejection of claims 6, 7 and 16 under 35 U.S.C. 103(a) as obvious over Wanek in combination with Quintero and further in view of Cavezzan should now be reversed.

C. Claims 12 and 17 Would Not Have Been Obvious over the Combination of Wanek and Quintero in view of Larson

Claims 12 and 17 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Wanek and Quintero in view of Larson.

The Examiner alleges that modifying the combination of Wanek and Quintero with the teachings of Larson achieves the features of claims 12 and 17. Appellants respectfully disagree with the allegations by the Examiner.

Appellants' submit that Larson does not remedy the deficiencies of the combination of Wanek and Quintero as set forth above with respect to claim 1, from which claims 12 and 17 indirectly depend, because Larson also fails to teach or suggest a step of subjecting the two components of dental molding materials in an unmixed state in a primary packing agent to

radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups.

Thus, Wanek, Quintero and Larson, taken singly or in combination, fail to teach or suggest a step of subjecting two components of dental molding materials in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups and further comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions, ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction, iii) ring opening polyether impression materials via an aziridino group or iv) polyether impression materials which are cross-linkable by condensation reaction as required by claim 1.

Accordingly, the combination of Wanek with Quintero and Larson could not possibly lead to Appellants' invention, and the rejection of claims 12 and 17 under 35 U.S.C. 103(a) as obvious over Wanek in combination with Quintero and further in view of Larson should now be reversed.

(8) CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that the rejections are in error and that claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are in condition for allowance. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1, 2, 6, 7, 9-12, 16, 17 and 19.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By /Brian C. Anscomb/

Brian C. Anscomb
Reg. No. 48,641
875 Third Avenue - 18TH Floor
New York, NY 10022
Phone: (212) 808-0700
Fax: (212) 808-0844

(9) CLAIMS APPENDIX

CLAIMS INVOLVED IN THE APPEAL:

1. Process for the sterilization and/or germ reduction of elastomeric two-component dental molding materials, said process comprising the steps of:

providing two components of the dental molding materials, wherein at least one component of the two components comprises a polymer having one or more functional groups, and further wherein the at least one component comprises:

i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions;

ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction;

iii) ring opening polyether impression materials via an aziridino group; or

iv) polyether impression materials which are cross-linkable by condensation reaction; and

subjecting the two components in an unmixed state in a primary packing agent to radiation sterilization.

2. Process according to Claim 1, wherein the two components are cross-linkable together.

3.-5. (Canceled)

6. Process according to Claim 1, which further comprises radiation sterilizing, in addition to said dental mold materials, an addition cross-linking silicon impression material, said addition cross-linking silicon impression material comprising vinyl-group-containing polysiloxanes, said vinyl-group-containing polysiloxanes comprising at least in part diphenyl siloxane- and/or phenyl methyl siloxane structural units.

7. Process according to Claim 6, wherein the addition cross-linking silicon impression material comprises a polymer comprising at least 3 Mol-% diphenyl siloxane and/or phenyl methyl siloxane units.

8. (Canceled)

9. Process according to Claim 1, wherein the two components are arranged in the primary packaging and are simultaneously radiation treated along with accessories for mixing or for application of the dental molding material.

10. Process according to Claim 1, wherein a twin-chamber cartridge is used as primary packaging and a mixing nozzle as accessory.

11. Process according to Claim 1, wherein the radiation sterilization is performed by means of gamma rays or electron rays.

12. Process according to Claim 11, wherein the radiation sterilization is performed at a radiation dose of a maximum of 50 kGy.

13.-15. (Canceled)

16. Process according to Claim 7, wherein the polymer comprises at least 10 Mol-% diphenyl siloxane and/or phenyl methyl siloxane units.

17. Process according to Claim 12, wherein the radiation sterilization is performed at a radiation dose of 20 to 30 kGy.

18. (Canceled)

19. Process according to Claim 1, wherein the one or more functional groups is a vinyl group and a SiH group when the at least one component comprises silicone impression materials or an aziridino group when the at least one component comprises polyether impression materials.

(10) EVIDENCE APPENDIX

None.

(11) RELATED PROCEEDINGS APPENDIX

None.